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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
32860-001070/US	

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on _____ Signature_____	First Named Inventor Klaus ABRAHAM-FUCHS et al.	
Typed or printed name _____	Art Unit 3686	Examiner Edward B. Winston III

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
   Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
   See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
   (Form PTO/SB/96)

☑ attorney or agent of record. 34,313
   Registration number _____.

☐ attorney or agent acting under 37 CFR 1.34.

   Registration number if acting under 37 CFR 1.34 _____

_____ Reg. No. 56,205
Signature

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Typed or printed name

(703) 668-8000
Telephone number

July 1, 2011
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Klaus ABRAHAM-FUCHS et al.	Confirmation No.:	8501
Application No.:	10/589,538	Examiner:	Edward B. Winston III
Filing Date:	August 16, 2006	Group Art Unit:	3686
Title:	METHOD FOR VERIFYING COMPLIANCE WITH A PERFORMANCE SPECIFICATION ASSIGNED TO A MEDICAL WORKING PRACTICE		
Attorney Docket:	32860-001070/US		

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Randolph Building
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July 1, 2011

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir or Madam:

In response to the Office Action dated March 3, 2011 and the Advisory Action mailed May 25, 2011, Appellants request that an appointed panel of Examiners (hereinafter "the Panel") review the pending rejections.

I.   MATERIAL UNDER REVIEW.

Claims 1-7 and 10-20 stand rejected under 35 U.S.C. § 103(a) as being anticipated Sabol et al. (US 2004/0122719) "Sabol," in view of Urquhart et al. (US 2004/0073454) "Urquhart."[1] Claims 8-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sabol in view of Urquhart and further in view of Miller et al. (US 5,446,653) "Miller."[2]

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[1] Final Office Action, U.S. Appln. No. 10/589,538, U.S. Pat. and Trademark Office, p. 2 (March 3, 2011).
[2] Id. at 9.

II. SABOL IN VIEW OF URQUHART FAILS TO RENDER INDEPENDENT CLAIM 1 OBVIOUS BECAUSE SABOL IN VIEW OF URQUHART FAILS TO DISCLOSE OR SUGGEST "STORING, BY A TEST SYSTEM, TEST CRITERIA FOR THE DATA, CORRELATED WITH THE PERFORMANCE SPECIFICATION."

Claim 1 is directed to a method for determining a degree of compliance with a performance specification assigned to a medical working practice. Claim 1 is provided below for the Panel's convenience.

> 1. A method for determining a degree of compliance with a performance specification assigned to a medical working practice, the method comprising:
>
> recording and storing, by a data-processing device, data correlated with the medical working practice;
>
> storing, by a test system, test criteria for the data, correlated with the performance specification;
>
> reading, via the test system, the data stored in the data-processing device; and
>
> evaluating, via the test system, the data with the aid of the test criteria and determining the degree of compliance with the performance specification.

Sabol discloses a medical resource processing system. The system may provide material to a patient such as "structured video and/or audio recordings of questions and answers." Paragraph [0332] of Sabol. The material provided is for the patient. Resources that can be processed include reference sources which represent information about "medical events, medical conditions, disease state," and financial information. As recited in paragraph [0052] of Sabol,

> The data resources do not, in general, require information to be gathered directly from the patient. Rather, these resources are more general in nature and may be obtained through data reference libraries, subscriptions, and so forth.

Thus, the data of Sabol represent general medical knowledge rather than a set of rules and performance specifications.

> To maintain the validity and quality of such data, the validation and data management module 324 may carry out specific functions, typically bi-directionally, as indicated in FIG. 22. Such functions may include those of the reconciliation modules as indicated at reference numeral 326, which can reconcile or validate certain data, such as based upon time of entry, source of the data, or any other validating criteria. Where such reconciliation or validation is not available, such as due to conflicting updates or inputs, such matters may be flagged to a user for reconciliation.

Paragraph [0352] of Sabol.

On page 3 of the Office Action, the Examiner relies on paragraphs [0004], [0008] and [0332] of Sabol to teach the "storing," of claim 1. However, paragraphs [0004], [0008] and [0332] of Sabol do not disclose or suggest "test criteria … correlated with the performance specification." For example, paragraph [0332] of Sabol discloses "structured video and/or audio recordings of questions and answers," not any criteria for implementing a test. Moreover, paragraph [0004] of Sabol recognizes various data acquisition techniques, but fails to recite storing "test criteria … correlated with the performance specification."

Consequently, Sabol fails to disclose or suggest the "storing, by a test system, test criteria for the data, correlated with the performance specification," as set forth in claim 1.

Urquhart discloses monitoring patient compliance with a prescribed drug regime. Monitoring devices are attached to drug dispensers and data about time and amount of drugs taken from the dispenser by a patient are collected. The data are subsequently transmitted to a server, where they are stored for analysis and later accessed by a physician. *See, e.g.,* paragraph [0014] of Urquhart.

However, neither Sabol nor Urquhart teach that the test criteria (i.e., the comparison between the recorded and prescribed dosage) are stored in a test system. According to Urquhart, said criteria are rather an intrinsic property of a processing device used for data analysis. For example, paragraph [0040] of Urquhart provides:

> PC 16 operates as a communication link to one or more remote stations. One such remote station is a PC 18 provided at a physician location. Another such remote station is a server 20, such as a webserver hosting the portal website designed to provide the analysis services discussed above. In particular, server 20 operates as a processing device which analyzes the received dosing history data and any information provided to the system by the physician and thereby generates analysis data used for a patient, including dosage histories, analysis of expected results of dosage history, treatment advice, and recommendations.

Consequently, one of ordinary skill in the art would hard-code the analysis criteria. As such, the analysis criteria are not stored by a test system. Therefore, Urquhart fails to disclose or suggest the "storing, by a test system, test criteria for the data, correlated with the performance specification," as set forth in claim 1.

Since both Sabol and Urquhart fail to disclose or suggest the "storing," of claim 1, Sabol and Urquhart, alone or in combination fail to render claim 1 obvious.

In the Examiner's response to Applicants' arguments on page 10 of the Office Action, the Examiner states that paragraph [0019] of Applicants' Summary provides that a degree of compliance <u>may lead to</u> a simple Yes/No decision. (emphasis added). In other words, a Yes/No decision may be made after determining a degree of compliance. <u>The degree of compliance cannot be interpreted as a simple Yes/No decision, as the Examiner has characterized the "degree of compliance."</u>

The Examiner points to paragraph [0289] of Sabol to support his contention that Sabol teaches the "degree of compliance." Relevant portions of paragraph [0289] are provided below for the Panel's convenience.

> The logic engine essentially contains the rules that coordinate the various functions carried out by the system. Such coordination includes accessing and storing data in the knowledge base, as well as execution of various computer-assisted data operating algorithms, such as for feature detection, diagnosis, acquisition, processing and decision-support. The logic engine can be rule-based, and may include a supervised learning or unsupervised learning system.

<u>Nowhere in the above-recited paragraph does Sabol disclose a degree of compliance.</u> The decision-support of Sabol does not disclose or suggest being a degree of compliance. The decision support can be any one of numerous factors which is not a "degree of compliance."

Moreover, the Examiner bases his opinion on the disclosure of a logic engine with the function of delivering "decision support." The description of said logic engine in paragraph [0289] of Sabol, however, is applicable to any general computing device. How the general functions are to be used in particular is gleaned from the context of Sabol. Usage of said decision support functionality to determine a degree of compliance between data and performance specification is not disclosed in Sabol. From the general context of Sabol, "decision support" is the presentation of data to a patient and/or physician, in order to aid them in making decisions. *See*, paragraph [0332] of Sabol.

As such, the Examiner has failed to establish a *prima facie* case of obviousness. Claims 2-7 and 10-20 are patentable at least by virtue of their dependency on claim 1.

For at least the foregoing reasons, Appellants respectfully request that the Panel withdraw the Examiner's rejection of claims 1-7 and 10-20 under 35 U.S.C. § 103.

III.   REJECTION OF CLAIMS 8-9.

The Examiner correctly acknowledges that the features of claims 8-9 are not disclosed or suggested by Sabo and Urquhart.   However, the Examiner alleges that these features are taught by Miller.   Even if Miller taught the features of claims 8-9 (which Applicants do not admit) and that Miller could be properly combined with Sabol and Urquhart (which Applicants do not admit), Miller fails to cure the deficiencies of Sabol and Urquhart as described above with reference to claim 1.   Therefore, Sabol, Urquhart and Miller fail to render claims 8-9 obvious.

IV.   CONCLUSION.

In view of the above remarks, Appellants respectfully request that the Panel withdraw the grounds of rejection and allow the pending claims.

Should there be any outstanding matters that need to be resolved in the present application; the Examiner is respectfully requested to contact the undersigned at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C

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